DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

d17066

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-42

April 3, 1998

Richard Peck, President
QTM, Inc.
300 Stevens Avenue
Oldsmar, Florida 34677

Dear Mr. Peck:

We are writing to you because on November 7, 10, and 12, 1997 FDA Investigator Christine M. Humphrey collected information that revealed serious regulatory problems involving the Tapsul esophogeal pill electrode which is manufactured by your firm (Class II) for Arzco Medical.

Under the Federal Food, Drug, and Cosmetic Act (The Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation which incorporates the device GMP.

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacture, processing, packing, storage, or distribution are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to use a validated test (1/2 lb. pull test) to determine the functional strength of the Tapsul Recording Pill, e.g., the pull test is a required in-process test that is not documented to ensure the continuity of various connections (FDA 483, Item #1).

Your firm's response to FDA 483, Item #1 is not adequate. No documentation has been received by this office to date that shows the validation was conducted and forwarded for our review as promised in your November 17, 1997 response signed by Pat Lamb, RMS, Inc.

- Failure to document continuity testing pursuant to procedures #03-0001-01 and 03-0028-01.

Your firm's response to FDA 483, Item #2 is not adequate. The response states that Arzco does not require in-process continuity testing nor are there established written procedures to conduct continuity testing. Five (5) complaints received by Arzco involved continuity failures in the device (FDA 483, Items #2 & 3). We believe that it is much simpler and more efficient to ensure a critical connection is made by testing it at the time it is made, rather than finding a defective device at the time of final testing or receiving a complaint of a defective device. Further, the response fails to provide any record of a change control procedure being followed and documented incorporating this change. There has been no further documentation provided addressing this observation since the promised correction date of January 30, 1998.

- Failure to establish and maintain procedures for sampling plans based on valid statistical methods, e.g., sampling plans documented under procedures #01-09-011, 03-001-01, and 03-0019-01 were not being followed.

Your firm's responses to FDA 483, Item #4 are not adequate because there has been no documentation submitted to show promised changes and that all changes conform to proper change control procedures.

- Failure to establish, document and maintain a quality system to include procedures for the following: (a) management responsibility, (b) purchasing controls, (c) quality planning (d) corrective and preventive action and (e) quality system records.

Your firm's response to FDA 483, Item #7 is not adequate because your firm manufactures a finished device in accordance with the specification developer's procedures including device testing, packaging and labeling. By regulation under 201(h) a device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar article or related article, including any component, part, or accessory which the TAPSUL electrode is. The CFR under 820.3(o) defines a manufacturer as any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturers include but are not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development. Since your firm manufactures the TAPSUL in total for the specification developer, your firm is a manufacturer and is required to conform to all regulations as they relate to your manufacturing activities including Quality System requirements under 21 CFR 820.20.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (FDA 483) issued to you at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter. Please let this office know in writing within 15 working days of receipt of this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, Florida District, 555 Winderley Place, Suite #200, Maitland, Florida 32751.

If you have more specific questions about the Quality System Regulation and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 475-4728.

Sincerely,

Douglas D. Tolen
Director, Florida District